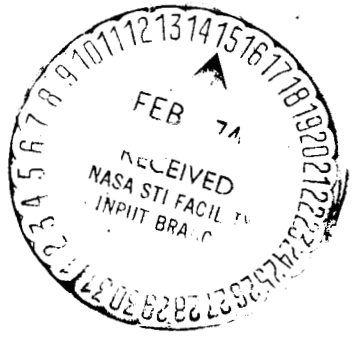
DOCUMENT NO. 65SD982

5 NOVEMBER 1965

ASSEMBLY/STERILIZER FACILITY FEASIBILITY PROGRAM

QUARTERLY PROGRESS REPORT NO. 1



GENERAL ELECTRIC

RE-ENTRY SYSTEMS DEPARTMENT

DOCUMENT NO. 65SD982

5 NOVEMBER 1965

ASSEMBLY/STERILIZER FACILITY FEASIBILITY PROGRAM
QUARTERLY PROGRESS REPORT NO. 1

21 JULY 1965 TO 21 OCTOBER 1965

CONTRACT NO. NASA 1-5381

PREPARED FOR

LANGLEY RESEARCH CENTER
LANGLEY STATION, HAMPTON VIRGINIA

APPROVED BY:

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GENERAL ELECTRIC

RE-ENTRY SYSTEMS DEPARTMENT
A Department Of The Missile and Space Division
3198 Chestnut Street, Philadelphia 4, Penna.

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I. SUMMARY

This is the first Quarterly Progress Report submitted in compliance with requirements of NASA Contract NASA 1-5381. The intent of this report is to delineate the progress accomplished and the objectives satisfied since the initiation of this effort on 21 July 1965.

The major milestones of this demonstration program accomplished during the first three months were the design of the Assembly/Sterilizer Analogue (A/S Analogue); the initiation of the test, demonstration and Bio -Assay Plan, the beginning of the test sample design and the detailed scheduling relative to this program.

A preliminary specification for the A/S Analogue was generated and a preliminary purchase order was negotiated. Plans for the receipt and installation of the A/S Analogue in the clean room have been reviewed and found satisfactory.

II. PROGRAM STATUS

A. PROGRAM TASKS

TASK 1. TEST SAMPLE

The test sample, Figure II-1, will be fabricated of an aluminum skin, two inches by four inches by thirty-two hundredths thick to which will be bonded a one quarter inch thick ESM heat shield contained in which will be a thermocouple. Mounted on this basic structure by means of brackets and supports will be a laminated glass printed circuit board containing the electronics circuitry which includes transistors, resistors, diodes, and capacitors. The test sample design has been completed.

The circuit of the test sample, Figure II-2, has been completed. As previously reported, the circuit was modified in order to present a more typical hardware-type representative of an unmanned planetary lander. This was accomplished by changing from a one-stage audio amplifier to a triggered multivibrator, concurred to by Langley technical representatives.

The test set, comprised of a signal generator and an output indicator, has been designed as illustrated in Figure II-3.

A breadboard of the test sample circuitry has been exposed to one cycle of sterilization, 24 hours at 135 degrees C., followed by a 20 hour life test. Measurements before and after exposure showed no measureable change in performance. See Appendix C.

The compilation of required purchase parts has been completed and all parts have been ordered during this reporting period. Fabrication of the printed circuit board has been initiated. Fabrication and assembly of these test samples has been scheduled.

The assembly, storage, and manufacture of the test samples through the cleaning operation, clean room and the A/S Analogue is illustrated in Figure II-4.

TASK 2. TEST PROGRAM AND DEMONSTRATION

The planning of the Test Program and Demonstration has been formulated and the test plan is being issued concurrent with this report.

The test plan describes a program to provide the initial demonstration of the feasibility of a facility which permits the decontamination and sterilization of spacecraft with the capability for subsequent check and adjustment, repair, and sealing in a biological barrier under sterile conditions. This is demonstrated using a reduced scale analogue of the Assembly/Sterilizer Facility. The test program is composed of three major types of tests:

- Sterilization Verification
- Manipulation Tests
- Feasibility Demonstration

These tests are described in detail in the Test Plan and may be summarized as follows.

The sterilization verification tests assure that the A/S Analogue chambers are achieving the required decontamination and sterilization, using the prescribed treatments. These tests consist of two complete cycles of operation of the A/S Analogue subjecting a total of 150 specially prepared specimens to the treatments of ETO/Freon decontamination, dry heat sterilization and wet heat sterilization. The specimens are stainless steel strips with known, high, resident population of viable microorganisms.

The manipulation test consists of a limited human factors test to determine the limitations imposed upon a worker performing assigned tasks using the A/S Analogue, and problems directly related to this work environment. In addition, tools suitable for sterile assembly and sterilization facility procedures will be investigated.

The feasibility demonstration consists of the performance of five cycles of A/S Analogue operation, including decontamination and sterilization; and checkout, repair, assembly, packaging, and recycle repair on a special component simulating typical spacecraft hardware. A total of 50 of these components are available for this program. The present plan calls for holding five of these for use by NASA Langley. In addition, 131 biologically seeded stainless steel strips will also be processed during these cycles of the demonstration.

Successful completion of this test program will demonstrate that the Assembly/Sterilizer System design concept can be successfully implemented in a reduced scale analogue facility and can satisfy all applicable biological and physical requirements.

TASK 3. BIO-ASSAY

The proceduresfor biological assay for the program have been determined and are defined in Appendix A of the test plan issued concurrent with this report. Biological assay will be performed in conjunction with the manufacture of the test samples (task 1) and the performance of the test program and demonstration (task 2).

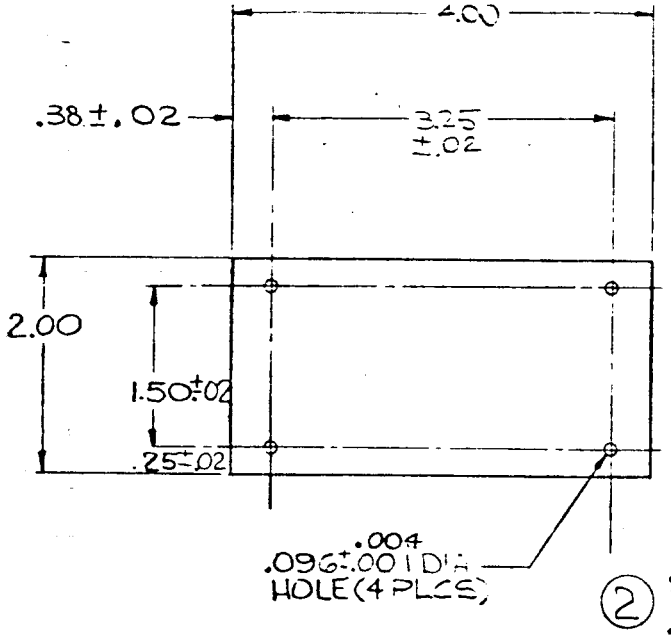
In the manufacture of the test sample, the clean work areas will be assayed by air sampling and fall-out monitoring. In addition, bio-assay of in-process parts and assemblies for the test sample will also be performed. The bio-assay points in the manufacturing flow are shown in the manufacturing flow diagram of Figure II-4.

In the sterilization verification, and feasibility demonstration of the test program and demonstration, bio-assay will be performed on test samples and stainless steel strips used as sterility control specimens. All of the S/C specimens will be seeded with viable organisms to achieve a resident population of 1×10^6, 1×10^8, or 1×10^{10}.

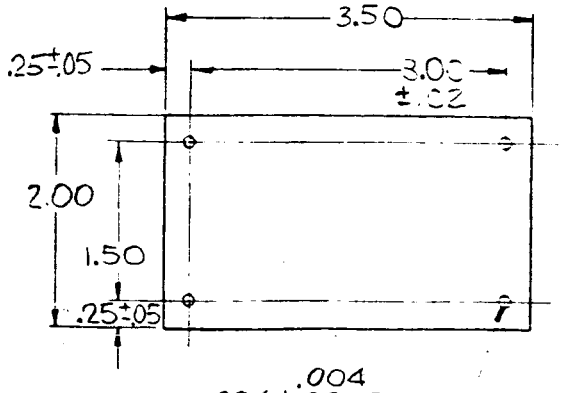
TEST SAMPLE FOR ASSEMBLY/STERILI

SK-56117-802

GENERAL ELECTRIC CO.
RE-ENTRY SYSTEMS DEPT.



② SKIN
.032 THK
ALUM-2024-T3



③ PRINTED CIRCUIT
.064 THK EPOXY G-

ER

NOTES:

1. ALL TOLERANCES ±.01 UNLESS OTHERWISE SPECIFIED.
2. INSTALL RIVETS PER 118A1508.
3. OPEN END-POP RIVETS. UNITED SHOE MACH. CORP. SHELDRON. CONN. 06435
4. ADHESIVE RTV560 WITH 0.5% T12 CALALYST (CLEAN & PRIME WITH GE4004 BEFORE APPLYING ADHESIVE.)
5. ESM 1CC4AP SERIES NOMINAL THICKNESS 1/4 IN.
6. HOLE FOR IRON CONSTAN THERMOCOUPLE TO BE HELD IN PLACE BY RTV 560.

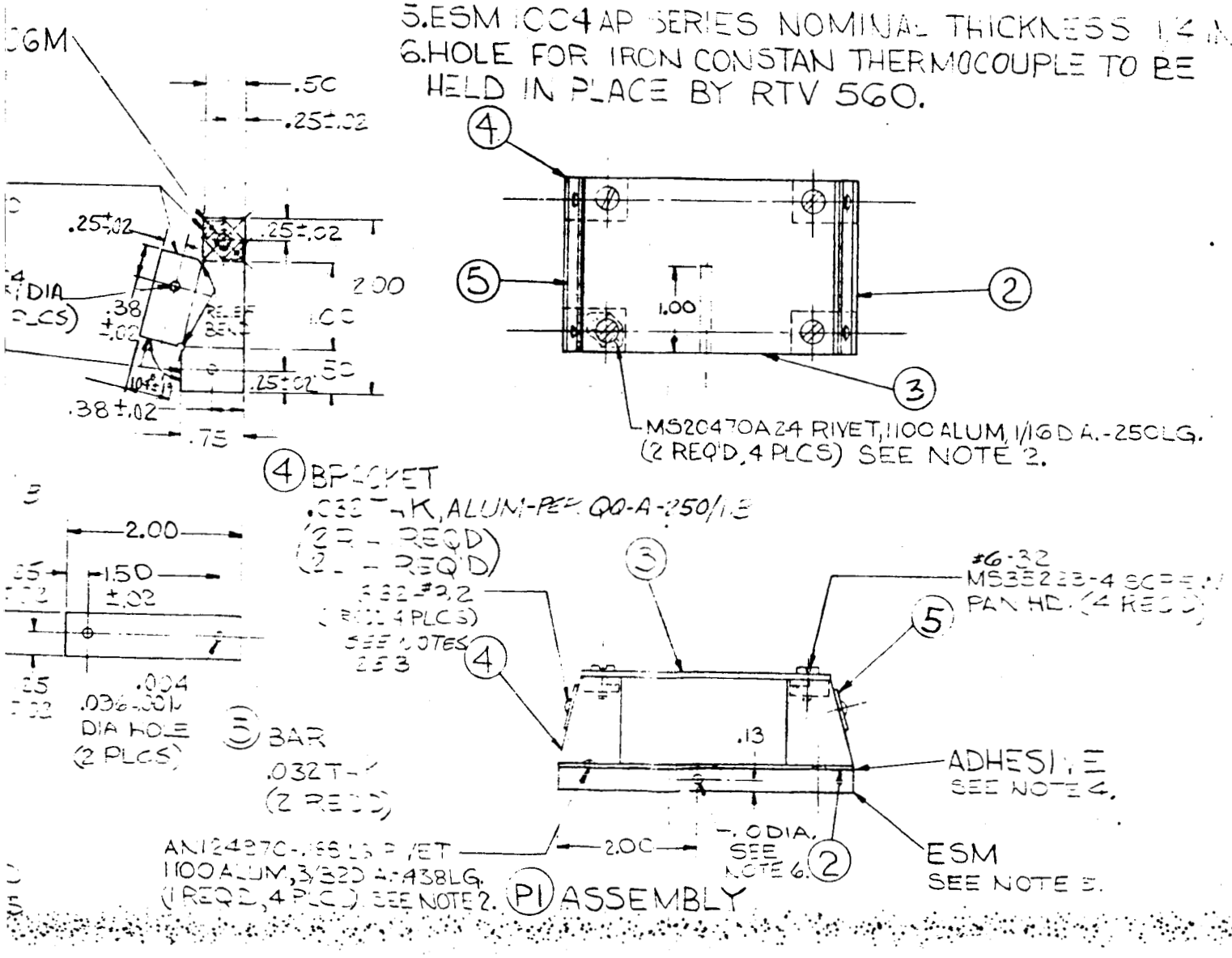
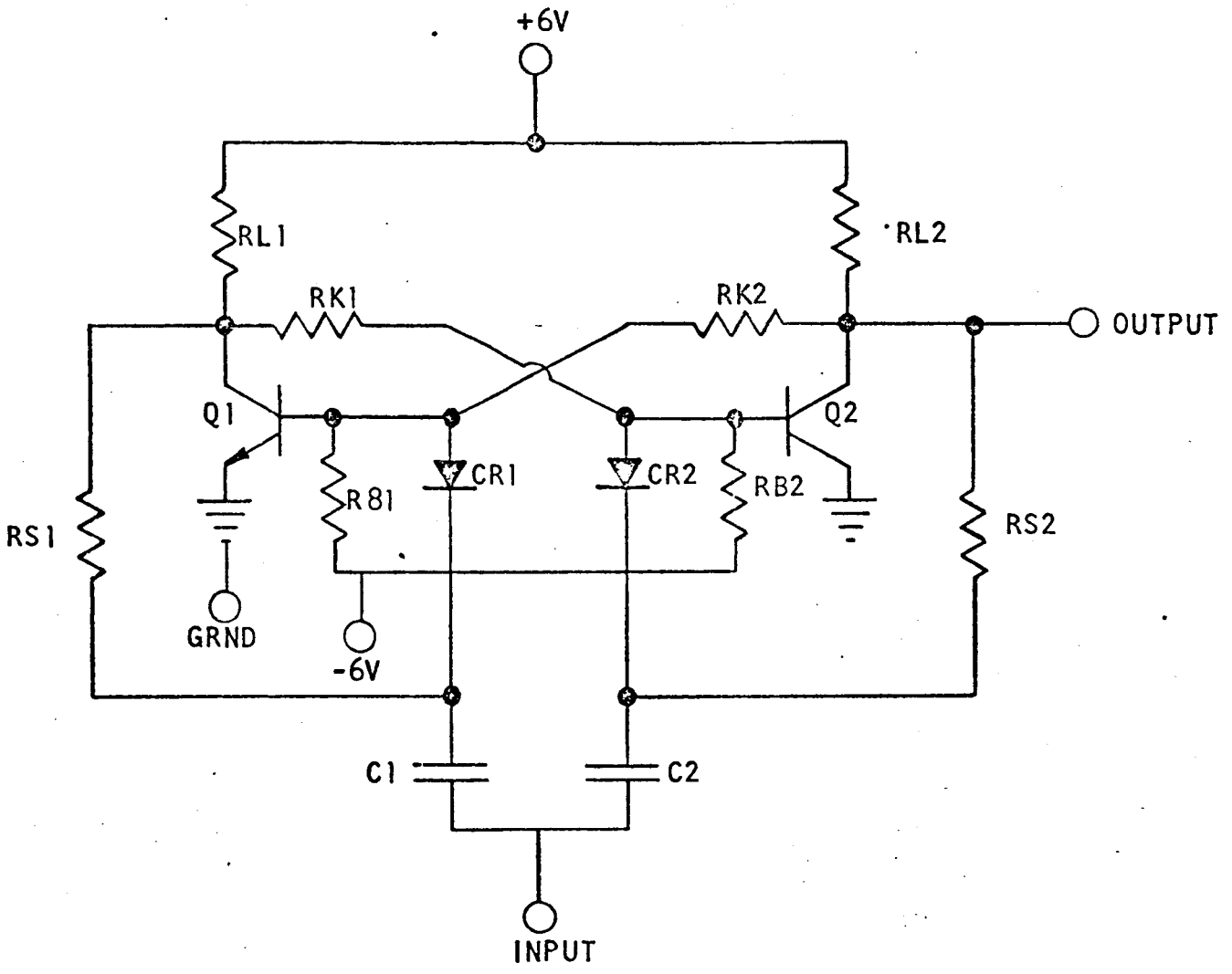


Figure II-1 - Test Sample



RL1,RL2 -- 1K, ± 5% RC07
RK1,RK2 -- 3.9K, ±5% RC07
RB1, RB2-- 100K, ±5% RC07
RS1, RS2-- 10K, ±5% RC07
C1, C2 -- 470 pF, CK05CW471K
Q1, Q2 -- 2N706
CR1,CR2 -- 1N914
5 Terminals R2574P2

Figure II-2 - Test Sample Circuit

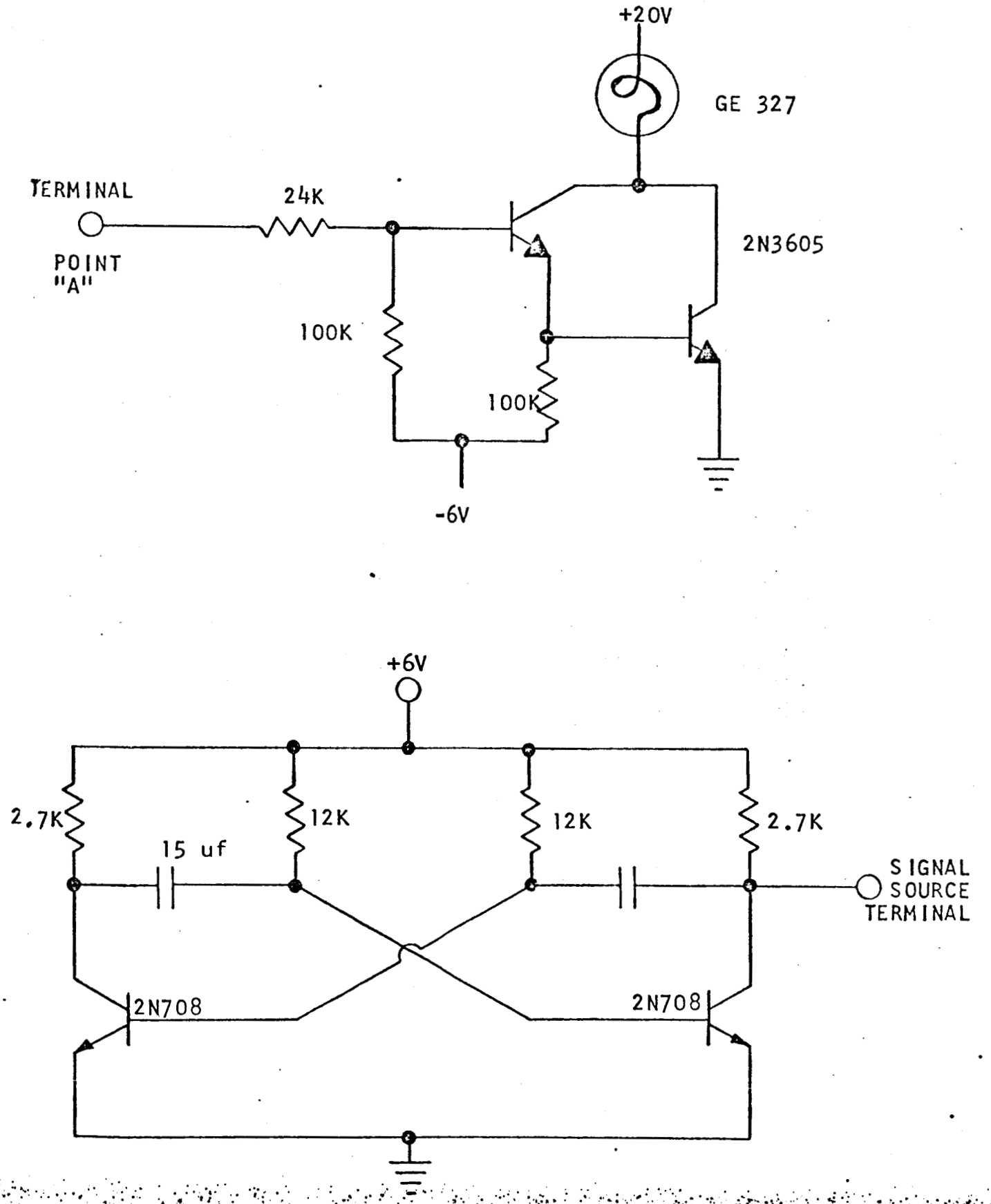
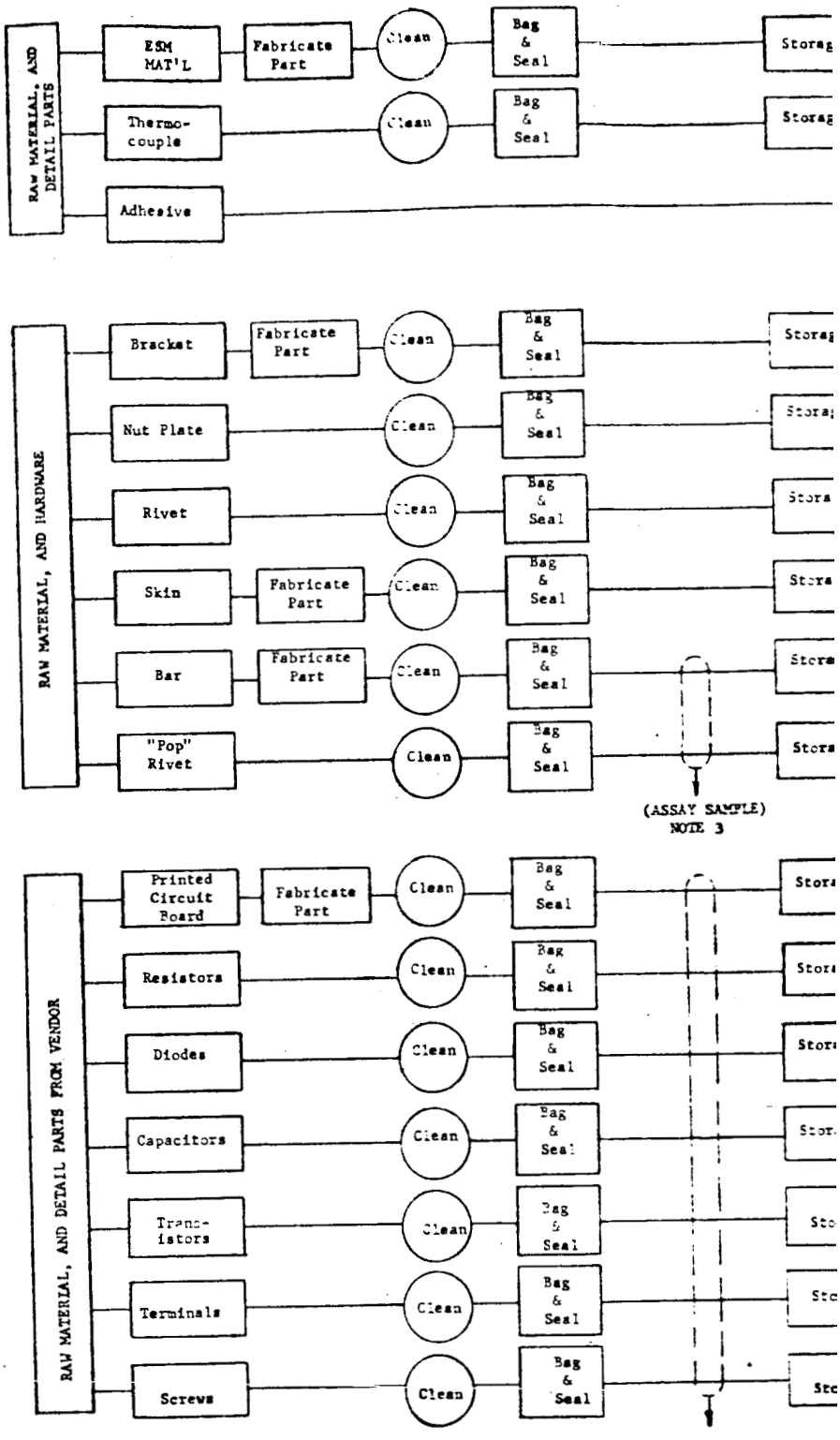
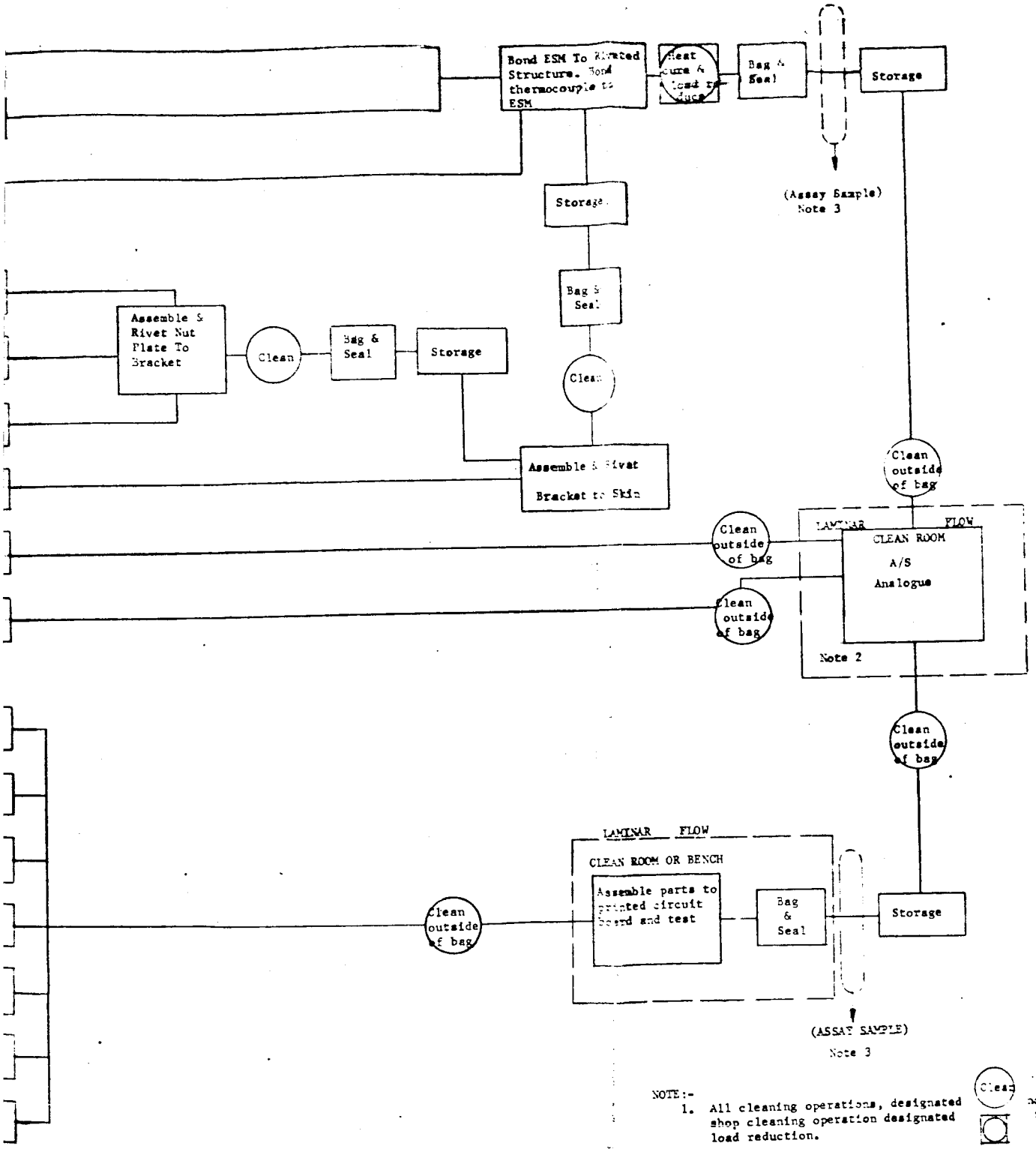


Figure II-3 - Test Sample Test Set


RAW MATERIAL, AND DETAIL PARTS
ESM MAT'L
Fabricate Part
Clean
Bag & Seal
Storag
Thermo-couple
Clean
Bag & Seal
Storag
Adhesive
RAW MATERIAL, AND HARDWARE
Bracket
Fabricate Part
Clean
Bag & Seal
Nut Plate
Clean
Bag & Seal
Rivet
Clean
Bag & Seal
Skin
Fabricate Part
Clean
Bag & Seal
Bar
Fabricate Part
Clean
Bag & Seal
"Pop" Rivet
Clean
Bag & Seal
(ASSAY SAMPLE)
NOTE 3
RAW MATERIAL, AND DETAIL PARTS FROM VENDOR
Printed Circuit Board
Fabricate Part
Clean
Bag & Seal
Resistors
Clean
Bag & Seal
Diodes
Clean
Bag & Seal
Capacitors
Clean
Bag & Seal
Trans-istors
Clean
Bag & Seal
Terminals
Clean
Bag & Seal
Screws
Clean
Bag & Seal



NOTE:-

1. All cleaning operations, designated Clean normal shop cleaning operation designated thermal load reduction.
2. The clean room operations performed in the Assembly Sterilizer analogue are part of the feasibility demonstration and described in section III of the test plan
3. In process bio-assays are performed in accordance with section of appendix A.

Figure II-4 - Assembly Flow of Test Sample

The seeding organisms will be B. subtilis var. niger or B. stearothermophilus.. After the decontamination and sterilization treatments and at the end of the operation cycles of the A/S Analogue, the S/C specimens and test samples will be assayed to ascertain the efficacy of the treatments and the capability of the A/S Analogue to maintain bio-integrity during performance of post-sterilization tasks on the test samples.

TASK 4. FULL SCALE FACILITY DESIGN STUDY

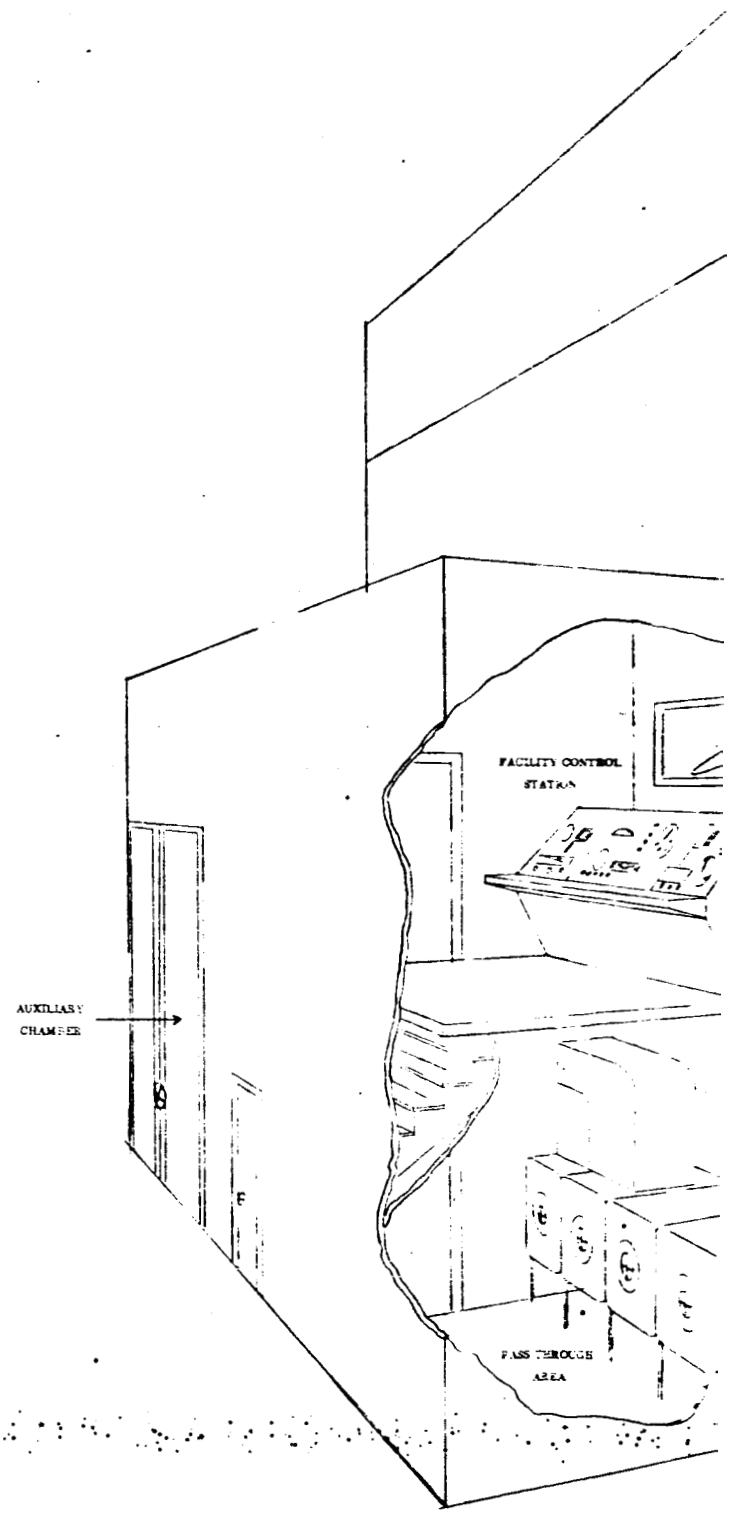
During this quarter, the full scale design study has concentrated on the suit for the facility and on one tentative physical layout of the facility.

The suit, with its tunnel and associated life support and communications equipment, has been designated the Bio-Isolator Suit System (BISS). A preliminary summary of design criteria for the BISS has been prepared to define ground rules for further investigation and study of the suit system. This summary is included herein as Appendix A.

The General Electric Company (RSD) has initiated a continuing series of discussions with firms presently engaged in work on space suits or special industrial suits. The aim of these discussions is to refine the criteria and to obtain preliminary indications of the critical areas in the design and fabrication of a BISS system compliant with these criteria. To date, approximately 10 present suit suppliers have been contacted.

The BISS suit system is found to differ in three major aspects from existing suit systems: It must withstand the environments of ETO/Freon decontamination and dry heat sterilization, permit entry through a tunnel, and operate with an inward pressure gradient.

The result of the physical layout survey of the full scale facility is shown in Figure II-5. This facility is sized to permit processing of Voyager-class satellite landing vehicles. The main chamber is 60 by 80 feet with an overhead of 45 feet. The auxilliary chamber is a 20 foot cube.


FACILITY CONTROL
STATION
AUXILIARY
CHAMBER
PASS THROUGH
AREA

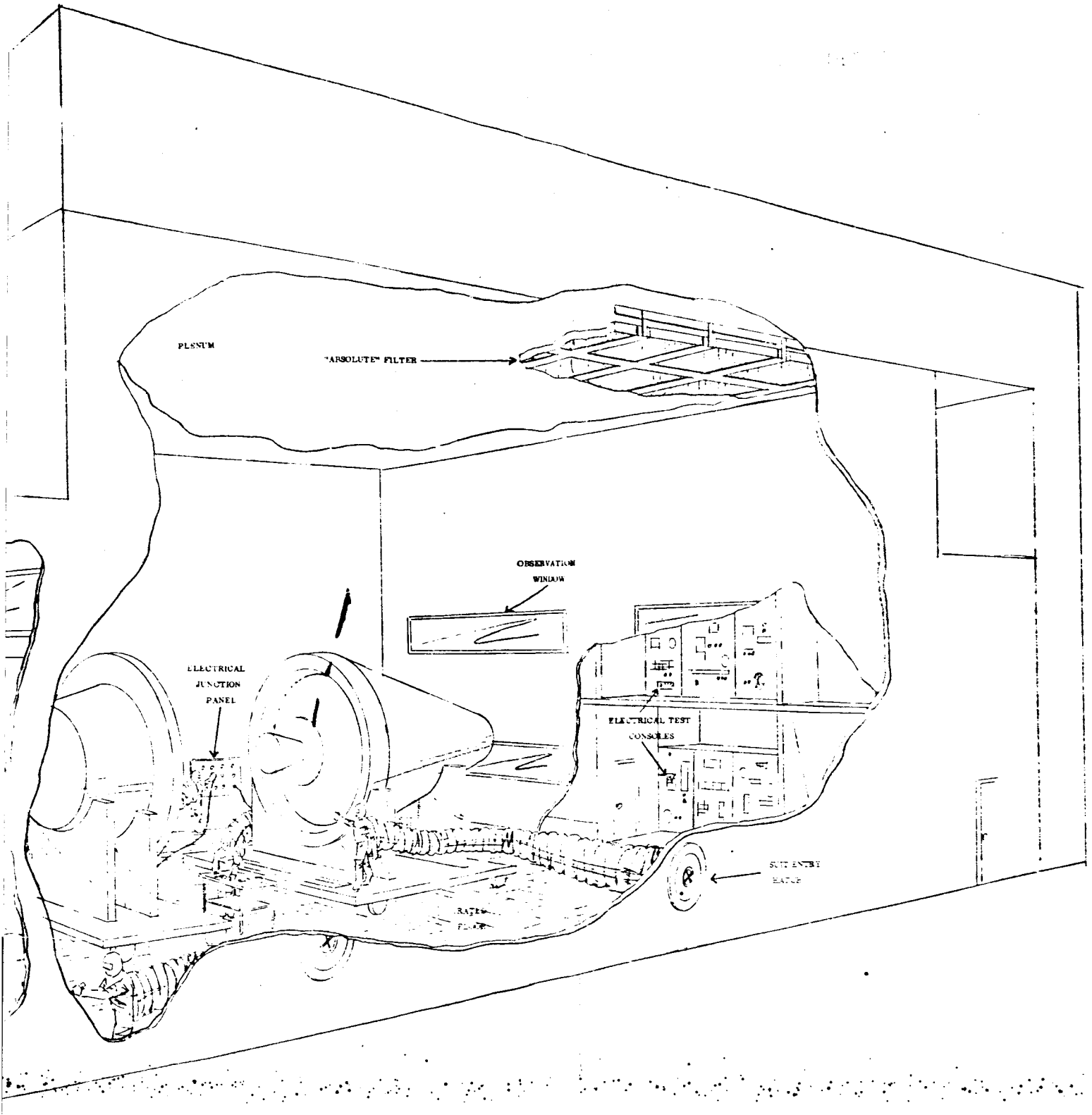


Figure II-5 - Full Scale Facility Design

B. FACILITY DEVELOPMENT (A/S Analogue)

The Assembly/Sterilizer Analogue.design has been finalized and the vendor, Kewaunee Scientific Equipment, has begun fabrication and assembly. Figure II-6 is a pictorial representation of the present design.

The Assembly/Sterilizer Analogue consists of three chambers - a main chamber, an auxiliary chamber, and an autoclave chamber. The main and auxiliary chambers will be controlled dry ovens and the autoclave will be a steam sterilizer. The main and auxiliary chambers will be capable of using either nitrogen or ethlyene oxide Freon-12 (ETO) as the recirculating gas. See Figure II-7.

Primary sterilization shall be performed by recirculating dry heated sterile nitrogen, at less than 1% relative humidity within the main chamber, using the laminar flow principle and maintaining positive pressure within the chamber at all times. Although nitrogen is the gas intended for normal use, the A/S Analogue will be compatible with the use of other gases such as ethylene oxide, helium and freon.

In addition, the auxiliary chamber and autoclave chamber will be used to sterilize components which will be introduced later into the sterile main chamber after the primary sterilization cycle has been completed.

Operating Temperatures and Humidities of the Main and Auxiliary Chambers - The operating temperature range of the main chamber will be controllable from 70°F. to 300°F., and the operating temperature range of the auxiliary chamber will be controllable from 100°F. to 300°F. The temperature at any point within the chambers will not deviate from the set temperature by more than ± 3.6°F. at any external temperature from 70°F. to 80°. The relative humidity in the chambers will be from 20% to 60% from 70°F. to 90°F. The relative humidity will be less than 1% from 200°F. to 300°F. When ETO is the recirculating gas, the temperature will be controllable between 100°F. and 150°F. to within ± 5°F. at a relative humidity between 50% and 60%. At no time will the relative humidity within either chamber exceed 60%.

Typical Thermal Load (contents within the chambers) design limits will be as follows;

8 lbs.	Phenolic Glas	Sp. Ht.	.35 BTU/lb./°F.
8 lbs.	Steel	Sp. Ht.	.107 BTU/lb./°F.
8 lbs.	Rubber	Sp. Ht.	.30 BTU/lb./°F.

Autoclave Chamber - The operating temperature range of the autoclave chamber will be controllable from 216°F. to 270°F + 5°F/-0°F. over a controllable pressure range from 2 to 30 psig. The chamber will be safety valved at 33 psig.

Typical Thermal Load (contents of autoclave) design limits will be as follows:

4 lbs. Phenolic Glass	Sp. Ht.	.35	BTU/lb./°F.
4 lbs. Steel	Sp. Ht.	.107	BTU/lb./°F.
4 lbs. Rubber	Sp. Ht.	.30	BTU/lb./°F.
12 lbs. Liquid	Sp. Ht.	1.0	BTU/lb./°F.

The temperature rate of change on heat up or cool down will be 25°F. to 50°F. per hour for the main and auxiliary chambers.

A flash heat exchanger to vaporize the Ethylene-Oxide Freon (ETO) used in the system will be provided. A 650°F., 1.5 second, incinerator will be provided to sterilize the make-up Nitrogen used in the system.

Main Chamber - The main chamber will be of welded construction and will be fabricated using 304 stainless steel. The nominal inside working dimensions will be 60" long x 24" deep x 30" high. All internal surfaces will be polished to a 16 micro inch or better finish. A nominal radius of 1/2" will be provided on inside bends and corners. All welds will be free of surface porosity.

Access doors to the inside of the main chamber will be located on both ends of the enclosure and will open outward. The dimensions of the doors will permit a 16" diameter disc to pass through the plane of the opening. (A rectangular door of not less than 12" wide by 16" high may be substituted).

The doors will be designed to insure a suitable seal in the closed position when subjected to the operating temperatures and pressures within the chambers.

A sloping observation window will be provided in the front of the main chamber and made from heat resistant, shatterproof, glass plate. The nominal dimensions of the window will be 50" long x 15" high. To aid in the retention of heat during the sterilization cycle, a removable cover may be used over the window. If such a cover is provided, two 8" ports, suitable for observation of the interior of the chamber, will be incorporated. All gaskets will be closed pore, smooth surface finish material.,

Interconnected electrical junction panels containing ten terminals each will be located inside and outside the main chamber on the back surface. The terminals will provide for banana plug and stripped wire connections between the inside and outside of the chamber. The terminals will be capable of carrying a minimum of 2 amperes at 110 volts rms. The contact resistance will not exceed 0.1 ohm at 50 micro-amperes dc.

Twenty permanent-type thermocouple connectors, Conax or equivalent, sheathed, 1/16" by three feet long will be provided inside the chamber. Ten will be located on the left-hand end of the chamber and the remaining ten on the right-hand end of the chamber.

Two sets of gloves will be provided with the chamber. The gloves will be made of a soft, pliable, leakproof material, and will be capable of repeated exposure to all the environments specified for the equipment.

The chamber will be capable of being purged with dry nitrogen until all of the air is removed. (Approximately 20 volume changes per hour). Flow rate meters will be provided. Provision will be incorporated for biological assay of the main chamber atmospheres.

The chamber will be capable of continuous recirculation of the gas at a pre-selected velocity between 10 and 90 fpm while maintaining the chamber in accordance with the environments specified in Operating Temperature and Humidity requirements. The makeup nitrogen gas will be incinerated prior to entrance to the main chamber. The gas line from the incinerator to the chamber will be sterilizable.

Two filters will be provided in the design of the main chamber. One, a pre-filter, will be located in the floor of the chamber and the other, a final filter, will be located in the top of the chamber. Both filters will be readily removable for cleaning or replacement without disassembly of the chamber. The filters will be such that the gas-borne particle count within the chamber will not exceed a total of 100 particles per cubic foot of 0.5 microns and larger.

The auxiliary and autoclave chambers will be attached to the back of the main chamber. The design of the doors between the auxiliary and autoclave chambers and the main chamber will be such that the doors can be readily opened with a gloved hand. The doors will open and slide in a horizontal plane. The floor of the main chamber will be a grating with openings of 1/2" square up to 1/2". by one inch.

The A/S Analogue will be so designed that the outside surface temperature of the chamber will not exceed 100°F at any operating temperature and an ambient temperature of 70°F to 80°F.

The main chamber will maintain a controllable pressure gradient equivalent to 4" of water. The chamber will not exhibit any leak greater than 10^{-5} scc/sec. of helium at a pressure equivalent to 4" of water, when measured with a helium leak detector.

Auxiliary Chamber - The auxiliary chamber will be designed and constructed in accordance with the requirements specified under the main chamber description, except that the approximate size shall be 10" square x 16" long. The access door to the auxiliary chamber will be located on the back of the chamber and will be of a size to permit complete uninhibited access to the chamber. Shelves will be provided so the work pieces may be withdrawn. The shelves will be capable of being withdrawn either into the main chamber from the front or out of the auxiliary chamber from the back.

Six thermocouples, Conax or equivalent, will be provided of sufficient length to allow the thermocouples to be disconnected from the chamber contents with the gloved hand when the shelves are withdrawn into the main chamber. The chamber will be capable of being purged with dry nitrogen until all of the air is removed. (Approximately 20 volume changes per hour). Flow rate meters will be provided.

The auxiliary chamber will be capable of recirculating the gas in a path independent of the main chamber and will not be laminar flow. One filter shall be provided in the design of the auxiliary chamber and will be capable of being removable for cleaning or replacement without disassembly of the chamber.

The floor of the auxiliary chamber will be designed to permit a gas flow rate from 10 to 90 fpm with a pressure in the chamber equivalent to 4" of water. The outside surface of the auxiliary chamber will not exceed 100°F at any operating temperature and an ambient temperature of 70°F to 80°F. The auxiliary chamber will maintain a controllable pressure gradient equivalent to 4" of water. The chamber will not exhibit any leak greater than 10^{-5} scc/sec. at a pressure equivalent to 4" of water when measured with a nelium leak detector.

Autoclave Chamber - The autoclave chamber will be a horizontal, vacuum pressure type vessel of approximately 18" diameter x 26" long, designed for operating pressures up to 30 psig. The autoclave chamber will be safety valved at 33 psig. All details of design, materials and construction will meet or exceed the requirements of the American Society of Mechanical Engineers code for unfired pressure vessels. The chamber will be of welded construction and fabricated using 304 stainless steel.

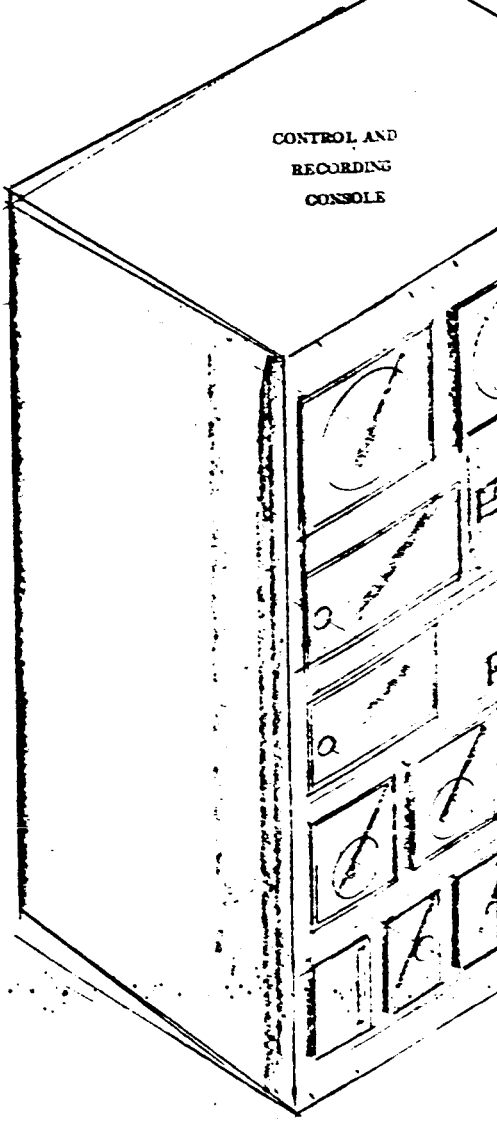
The access door to the autoclave chamber will be located on the back of the chamber and will be of such a size as to permit uninhibited access to the chamber. The door will be of the radial locking arm type. Shelves will be provided inside the chamber and will be capable of permitting the work pieces to be withdrawn.

Six thermocouples, Conax or equivalent, of sufficient length to allow the thermocouples to be disconnected from the autoclave contents with the gloved hand when the shelves are withdrawn into the main chamber will be supplied.

The autoclave chamber will have a drain line with a thermostatic trap. An adjustable valve will be provided to adjust the exhaust rate from 2 to 20 minutes.

The autoclave chamber will be capable of being purged with dry nitrogen (approximately 20 volume changes per hour). After the cooling cycle, and during purging, the autoclave will maintain a positive pressure relative to ambient.

The rate of steam admission will be capable of raising the autoclave chamber pressure from 28 mm Hg to 30 psig in five minutes with an empty chamber. A low water level cut-off will be incorporated into the design of the steam generator.


CONTROL AND
RECORDING
CONSOLE

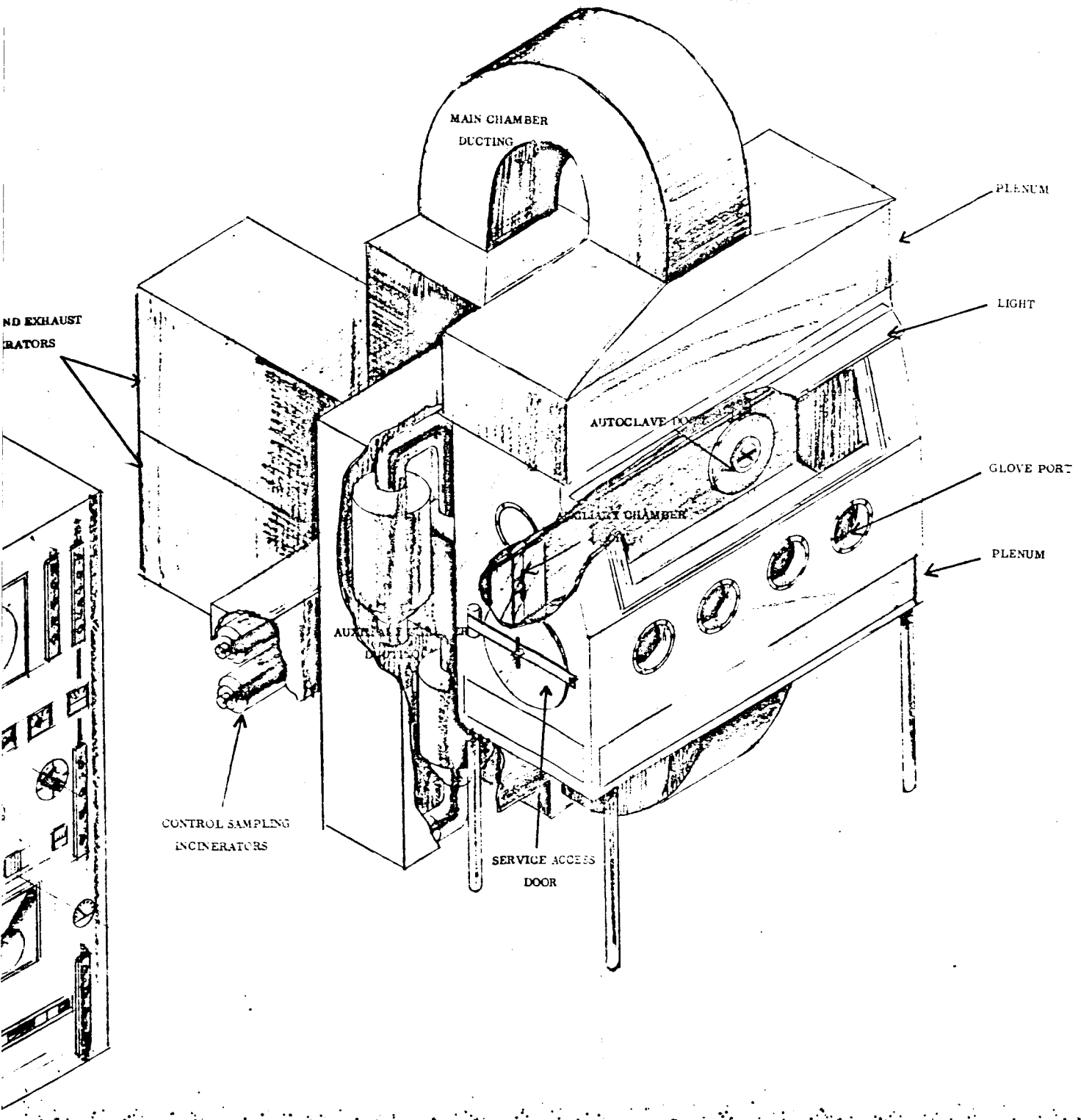


Figure II-6 - Assembly/Sterilizer Analogue

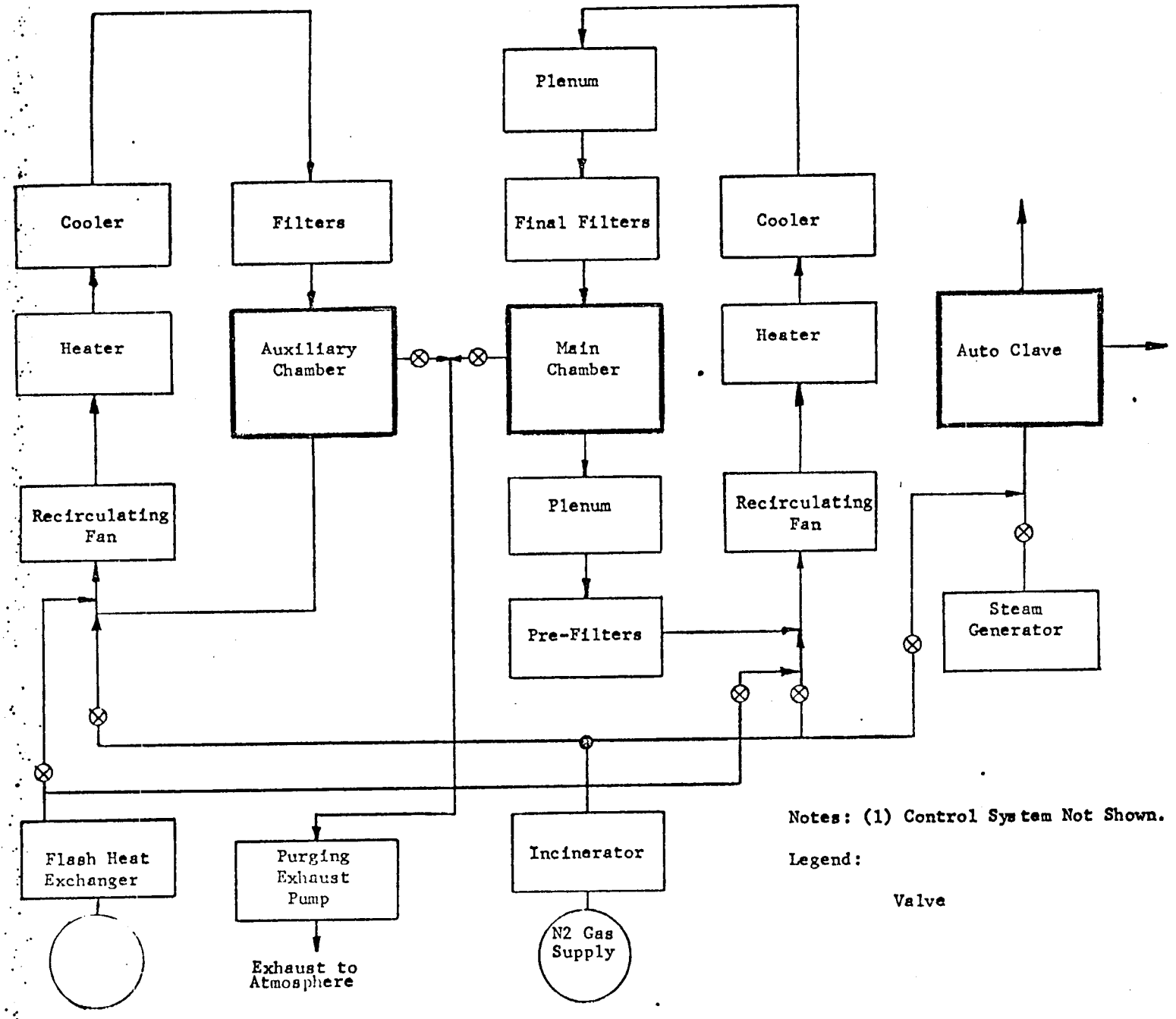


Figure II-7 - Assembly/Sterilizer Environmental Control Block Diagram

III. ACTIVITY PLANNED FOR NEXT QUARTER (THROUGH 21 JANUARY 1966)

A. PROGRAM TASKS

TASK 1. TEST SAMPLE

During the next quarter, the test sample fabrication and acceptance testing will be completed. The semi-assembled test samples will be sealed in bags and held in controlled stock ready for the performance of the feasibility demonstration of Task 2. The manufacturing flow for the fabrication of these samples is presented in Figure II-4.

TASK 2. TEST PROGRAM AND DEMONSTRATION

During the next quarter, the detailing of the test plan will be continued to provide necessary instructions for workers who will operate the Assembly/-Sterilizer Analogue. Training programs will be initiated to indoctrinate these personnel in the procedures required for the processing of sterile hardware and to become familiar with the Assembly/Sterilizer Analogue concept and operation.

The clean room will be prepared for installation of the Assembly/Sterilizer Analogue. This will include the provision of necessary services and utilities and a disposal system to process gases purged from the Assembly/-Sterilizer Analogue and the water from the chamber coolers.

TASK 3. BIO-ASSAY

Biological assay materials will be accumulated and Sterility Control Specimens will be fabricated. These specimens will be prepared by seeding with known organisms as described in Appendix A of the Test Plan. The resident population will then be counted and the storage stability of the population will be ascertained by biological assay.

The biological assay procedures, defined in the Test Plan Appendix A, will be detailed to instructions for the biological technicians performing the assays in the test program and demonstrations. These technicians will also participate in the indoctrination in the Assembly/Sterilizer Analogue concept and operation.

During the manufacture of the test samples, the clean work areas and the in-process test samples will be bio-assayed in accordance with the procedures defined in Appendix A of the Test Plan.

TASK 4. FULL SCALE FACILITY DESIGN STUDY

During this quarter, the study will be continued. Alternate layouts of the facility will be considered and a tentative selection of the most desirable layout will be made. Floor plans and preliminary elevations for this layout will be prepared.

The requirements of the full scale facility will be defined in a preliminary facility criteria summary which will define the technical ground rules for the continuing study.

Block diagrams will be prepared describing the flow of gases into, through and out of the facility, and also to describe the control systems necessary to maintain the atmosphere environments as defined in the criteria summary.

A preliminary operating plan will be prepared describing the sequence of events encountered during the operation of the full scale facility.

B. FACILITY DEVELOPMENT

During the quarter, the Assembly/Sterilizer Analogue fabrication and assembly will continue preparatory to acceptance tests at the subcontractor's plant.

A detailed performance test specification will be prepared for acceptance testing of the Assembly/Sterilizer Analogue at the subcontractor's plant and also for checkout of the installed facility at General Electric Company, Re-entry Systems Department, Philadelphia, Pa. These tests will be based on physical measurement of the Assembly/Sterilizer Analogue performance including the capability of isolating the atmosphere inside the analogue from the ambient environment. This isolation will be measured by a leak detection process using a readily detectable gas such as helium or FREON. The isolation measurements, based on leak tests, will be confirmed by biological testing in the Test Program and Demonstration.

IV. PROBLEM AREAS

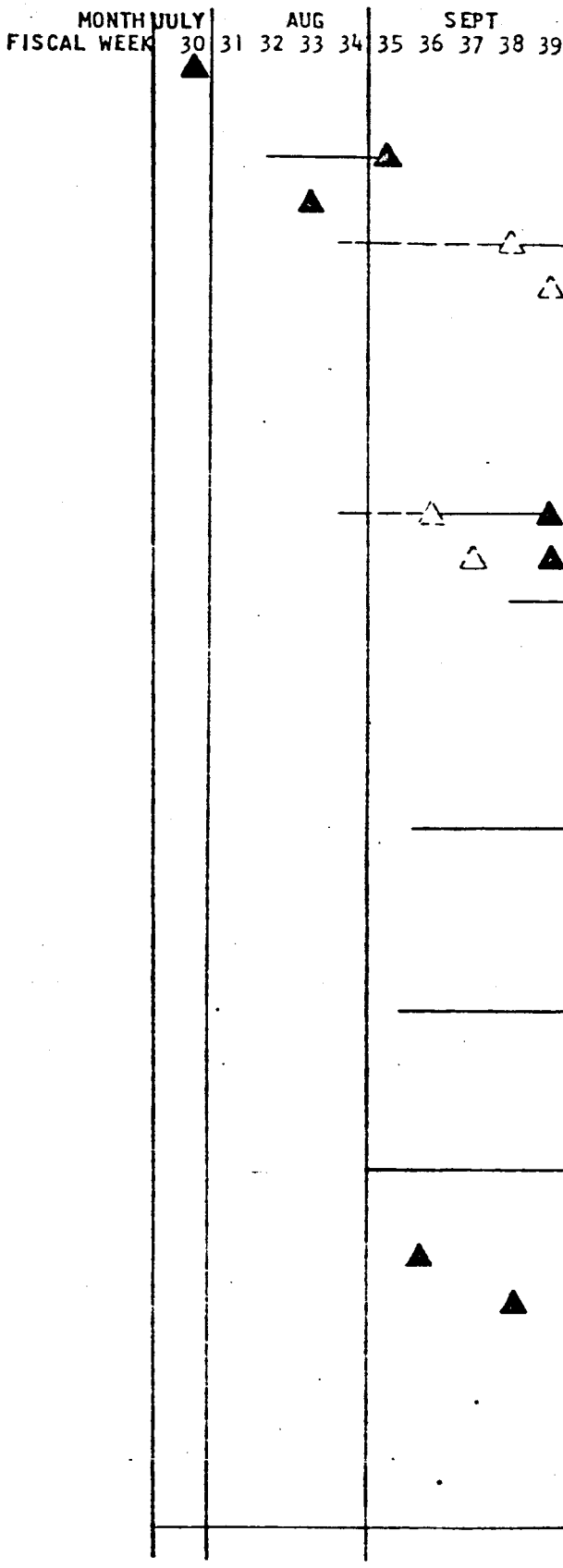
The only problem that has occured during the first quarter involved the delivery schedule of the A/S Analogue to GE-RSD by the subcontractor. This delivery has been rescheduled for two months later than previously scheduled. This problem was apparent during the second month of the program and was reported in the Second Monthly Report. At that time, however, the delivery delay was not expected to be extended as long as two months.

The schedule problem derived basically from two sources; subcontract's overly optimistic planning and subcontractor difficulties in obtaining commitments from his suppliers. The latter has been particularly difficult to overcome due to the fact that every major assembly in the analogue is a special item which must be specially fabricated for the program or an "off-the-shelf" design that must be modified.

The delivery date has been negotiated with the subcontractor, and he has given assurance of meeting the re-scheduled date.

In view of the slippage in delivery of the A/S Analogue and the importance of this item directly related to contract performance, the program activities have been re-scheduled encompassing the new date while still providing a logical program activity sequence.

The effect of this delay in the delivery of the A/S Analogue will be to extend the completion date of the demonstration program to week 24, and the final report to week 26. A program schedule showing revised schedule dates is shown in Figure IV-1.



PROGRAM GO-AHEAD

I. A/S ANALOGUE
   a) PREPARE SPECIFICATION
   b) SUBCONTRACTOR GO-AHEAD
   c) DESIGN
   d) DESIGN REVIEW
   e) FABRICATION
   f) ACCEPTANCE AT SUBCONTRACTOR
   g) DELIVER, INSTALL & CHECKOUT

II. TEST SAMPLE (CONTRACT TASK 1)
   a) DESIGN
   b) DESIGN REVIEW
   c) ENG. MODE 1 & TESTS
   d) FABRICATION
   e) ACCEPTANCE TESTS

III. MANIPULATION TEST, STERILIZATION VERIFICATION, & FEASIBILITY DEMONSTRATION (CONTRACT TASK 2
   a) TEST PLANNING
   b) MANIPULATION TESTING
   c) STERILITY VERIFICATION
   d) FEASIBILITY DEMONSTRATION

IV. BIOASSAY (CONTRACT TASK 3)
   a) ASSAY PLANNING
   b) ASSAY PERFORMANCE

V. FULL SCALE FACILITY DESIGN STUDY (CONTRACT TASK 4)

VI. REPORTING
   MONTHLY LETTER REPORT
   MONTHLY FINANCIAL REPORT
   TEST PLAN
   QUARTERLY PROGRESS REPORT
   FINAL ORAL PRESENTATION
   FINAL REPORT

VII. CONTRACT ADMINISTRATION

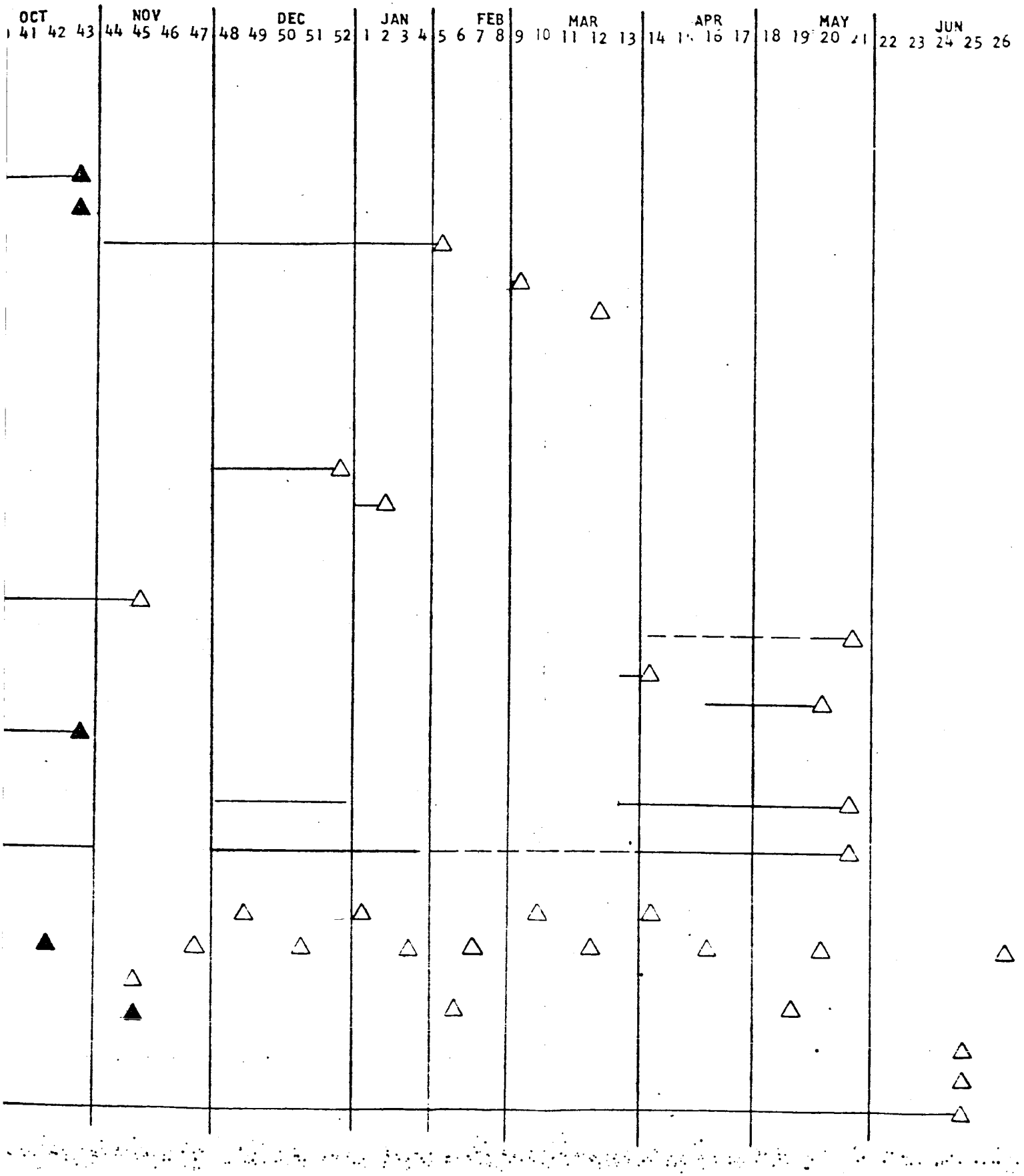


Figure IV-1 - Program Schedule

V. TRIPS AND VISITS

9 September	J. Crawford	GE to KSE
23 September	R. Hueshen Discuss Test Samples and General Test Components	LRC to GE
28 September	G. Von Wahlde and G. Saunders	KSE to GE
1 October	J. Crawford et al. Presentation	GE to LRC
20 October	G. Von Wahlde	KSE to GE

APPENDIX A

PRELIMINARY BISS SYSTEM CRITERIA SUMMARY

A. CONFIGURATION

The configuration is not restricted except that concept shall be consistent with Figure I and the suit and tunnel shall be inside the sterile area; the life support subsystem equipment, other than that in the suit or tunnel, shall be outside the sterile area. The suit and tunnel may be a permanently sealed single unit or the suit may be detachable (for maintenance but not operationally). The design may include a "suit within a suit" if this is the best solution to achievement of functional requirements. The skin of the suit and tunnel may be of single layer or laminated construction. As a design objective, the suit shall accommodate male technicians covering the maximum range of height and weight, and other critical anthropometric parameters, which can be included without creating fit discrepancies of sufficient magnitude to affect performance of the most deviant acceptable worker. If the tunnel is not self-supporting when fully extended with a man in the suit performing normal physical tasks (not lying down), the configuration shall include tunnel support by using light weight telescoping boom or similar means.

B. BIO-INTEGRITY

The bio-integrity of the suit and tunnel shall be demonstrated by helium leak test. Alternative measurements of bio-integrity will be considered. At no time shall the barrier between the sterile area and the outside be interrupted. The suit and tunnel must be highly impervious to puncture, rupture, or other failure which would violate the barrier. When operated in accordance with the requirements herein, the BISS shall have a probability of less than one chance in 10^5 of permitting microbial penetrations.

C. TECHNICIAN ENVIRONMENT

The system shall provide a healthful, comfortable environment for the technician in the suit performing light manual labor. As a minimum, the system shall provide control of: (1) gases breathed or in contact with the body (including removal of noxious or toxic gases), (2) humidity of gases breathed or in contact with the body, (3) temperature of gases breathed, and (4) body temperature of the technician. Suit inside pressure shall be nominally room ambient (i.e., 4 inches of water less than the sterile area). Consideration shall be given to providing the technician limited quantities of drinking water. There are no requirements for waste management.

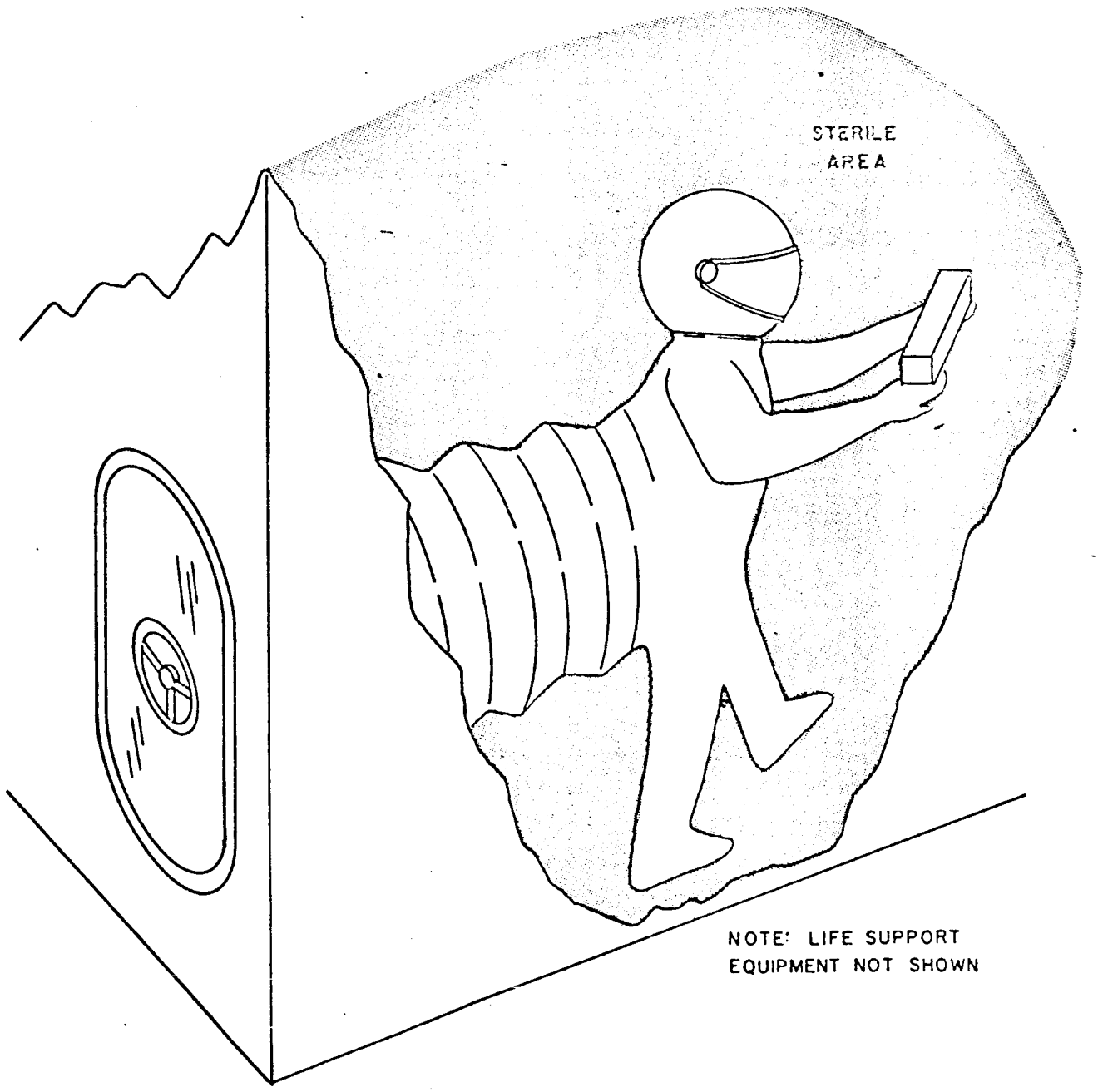


Figure I. Conceptual Sketch of the Bio-Isolator Suit System

D. TECHNICIAN SAFETY

The highest priority in the design of the system shall be given to the safety of technician in the suit. This shall include, as a minimum, reliability of life support equipment and emergency provisions for a technician to leave the suit through the hatch rapidly, aided or unaided. Consideration shall be given to rapid removal of a faint or unconscious technician from the suit. At no time will a man in a suit be alone in the sterile main chamber of the Assembly/Sterilizer; and at no time will a man be in the suit without back-up personnel outside the sterile area.

E. HUMAN FACTORS

The system shall be designed to high standards of human engineering practice.

1. ENTRY AND EGRESS

The design shall provide maximum ease of entry to and egress from the suit through the tunnel. It is anticipated that the tunnel will be contracted during entry and egress. Any specialized equipment required to aid entry or egress shall be considered as part of the system.

2. VISIBILITY

The design shall not limit the visibility of the technician either by obstruction or by aberration. Provision shall be made for the prevention of fogging of the face plate. The design shall accommodate a technician wearing eyeglasses.

3. MOBILITY

The design shall permit maximum mobility of the technician with free movement of all body joints. The technician shall be capable of unrestricted movement throughout a semi-circular region up to at least 20 feet from the hatch. Consideration shall be given to increasing this distance to 60 feet. The design shall permit the technician to circle back so that the tunnel forms a rough circle from the hatch to the suit. The mobility shall be sufficient to permit one suited worker to assist a second one in emergency removal of a man from the chamber.

4. MANUAL DEXTERITY

The suit shall not significantly reduce the technican's manual dexterity.

5. COMMUNICATION

The design shall incorporate provisions for oral communication between the technician and personnel outside the sterile area and between technicians in two or more suits in the sterile area.

F. HYGIENE

In addition to satisfaction of the requirements of Paragraph C above, the system shall incorporate provisions for exchange of technicians with a minimum of delay and without presenting offensive or unhygienic conditions for the second technician. Satisfaction of this requirement may require an approach of a "suit within a suit."

G. EQUIPMENT ENVIRONMENT

1. OUTSIDE STERILE AREA

The environment outside the sterile area shall be assumed to be a minimally air-conditioned industrial environment for both operating and nonoperating conditions.

2. INSIDE THE STERILE AREA

The sterile area will be at a pressure of four inches of water above the pressure inside the suit.

The equipment inside the sterile area shall be designed to withstand repeated exposure to dry heat (nominally 1% RH or less) in an inert atmosphere (N_2) at temperatures up to 300° F and exposure to ethyleneoxide/freon 12 (12%/88%) at temperatures up to 150° F at one atmosphere pressure (absolute). (The technician is not in the suit under these conditions.) Retention of ETO by the suit after this cycle shall be less than 900 parts per million in the suit material in contact with the worker and shall not cause ETO contamination of the suit atmosphere greater than 50 parts per million.

The suit and tunnel outer surface cleaning shall consist of scrubbing with detergent, rinsing with water then wiping down or spraying with a microbicidal agent such as 70 percent ethanol or isopropanol at ambient temperature.

An additional environment for the soles of suit feet is abrasion by the floor of the sterile area which is a grating with nominal openings of one to two inches square and a nominal web thickness of 1/8 inch or less. Abrasion by this grating is also an environment for the suit and tunnel if a suited worker falls.

With the worker in the suit, the sterile area shall have a temperature of 70° to 80° F and a relative humidity of less than 50 percent.

3. INSIDE THE SUIT AND TUNNEL

The environment inside the suit and tunnel shall be the technician environment (Paragraph C above) when the worker is in the suit.

When the worker is not in the suit, the special environments are cleaning and suit sterilization. Suit inner surface cleaning will include detergent wash, rinsing with water, wiping down or spraying with a microbicidal agent such as 70 percent ethanol or isopropanol. When the outside of the suit is being sterilized, the inside of the suit will reach a temperature of up to essentially 300° F. During this treatment the gas in the suit will be air of normal atmospheric composition.

H. BISS ENDURANCE

The system shall be designed for not less than (later) hours of continuous trouble-free operation without maintenance beyond replacement of filters or expendable supplies in the life support subsystem. The equipment of the system other than the suit and tunnel shall be designed for a total life of not less than (later) hours. The suit and tunnel may be replaced at shorter intervals.

The suit, tunnel, hatch, and all equipment integral thereto shall be capable of withstanding, without violation of any design criteria, 20 cycles each of dry heat, ETO/freon, and cleaning as described in Paragraph G.2.

I. STERILE MAINTENANCE

The design shall permit at least one replacement of the tunnel and suit without jeopardizing the sterility of the sterile area.

APPENDIX B

TYPICAL OPERATING PLAN

I. A/S ANALOGUE PREPARATION

Prior to its use as a facility for sterilization, assembly and checkout of equipment, the A/S Analogue will be put through a rigorous cleaning, preparation checkoff and bio-load reduction cycle.

A. Cleaning

1. Open all A/S Analogue doors and remove all removable items such as racks, tools, and filters.

2. Scrub all external surfaces with detergent solution followed by distilled water rinse and decontamination with 70% ethanol or 70% isopropanal

3. Clean all removable items as in (2) above.

4. Clean all accessible internal surfaces, as in (2) above, working from innermost parts outward installing removable items as appropriate stages of cleaning. Close off each section as it is cleaned.

   NOTE: Examine filters carefully for cleanliness and condition before installing.

B. Check-Off

The check-off procedure will be defined later.

C. Bio-Load Reduction

After cleaning and check-off, the main chamber, auxiliary chamber, and autoclave will be subjected to sterilization cycles for biological load reduction.

The load reduction cycles for the main and auxiliary chambers shall be dry heat cycles as specified below. (ETO/Freon may be employed at the option of the director of A/S Analogue operations).

The Load reduction cycle for the autoclave shall be the dry load cycle described below.

II. MAIN CHAMBER OPERATION

A. Set-up and Leak Check.

1. Place equipment to be sterilized, tools, test cables, etc., in the chamber in such a manner as to maximize contact of the chamber atmosphere with the chamber contents and to minimize disturbance of the subsequent laminar flow. Connect thermocouples to the thermocouple junction panel and attach the sensing end to the equipment in the chamber. The equipment may be passed into the main chamber through the end doors, the auxiliary chamber, or the autoclave.

2. Close and seal the end doors of the chamber and inner doors of the auxiliary chamber and autoclave.

3. Initiate the laminar flow.

4. Purge the air from the chamber and fill it with helium to a pressure of 4" of water above ambient. Check gloves and all seams and seals for leaks using a helium leak detector or equivalent. Total leakage at any one point shall not exceed 10^{-5} scc/sec.

B. ETO/Freon Cycle

1. Perform IIA above for set-up and leak check.

2. Maintaining laminar flow of the chamber atmosphere, purge the helium from the chamber and fill it with ETO/Freon (12%/88%) to a pressure of 4" of water above ambient, (nominally 20 changes of gas).

3. Raise the chamber temperature, at a rate of 25°F. to 50°F per hour, to the preselected temperature in the range of 100°F. to 150°F., maintaining chamber pressure by bleed-off.

4. Maintain the selected chamber temperature for a period of 2 to 24 hours (2 hr. at 150°F., 24 hr. at 100°F.). The chamber pressure and a relative humidity of 50% to 60% shall also be maintained.

5. At the completion of the high temperature dwell, return chamber temperature to ambient at a rate of 25°F. to 50°F. per hour, maintaining chamber pressure by make-up with ETO/Freon.

6. Maintaining a positive chamber pressure, purge the ETO/Freon from the chamber and fill with sterile nitrogen to a pressure of 4" of water above ambient. (nominally 20 changes of gas). When the nitrogen atmosphere has been established, the relative humidity shall be 20% to 60% at ambient temperature. It will probably be necessary to cool the recirculating gas during the nitrogen fill to prevent overheating the chamber contents.

NOTE: It shall be possible to maintain the chamber for an extended period in the state it is left in immediately following steps 5 or 6. Chamber pressure shall be maintained by make-up with ETO/Freon or sterile nitrogen respectively.

C. Dry Heat

The dry heat cycle may be performed either after set-up and leak check or after the ETO/Freon cycle in the main chamber.

Omit steps 1 and 2 below if ETO/Freon cycle precedes dry heat.

1. Perform IIA above for set-up and leak check.

2. Maintaining laminar flow of the chamber atmosphere, purge the helium from the chamber and fill it with sterile nitrogen to a pressure of 4" of water above ambient (nominally 20 changes of gas). It may be necessary to cool the recirculating gas during the nitrogen fill to prevent overheating of chamber contents. When the nitrogen atmosphere has been established, the relative humidity shall be 20% to 60% at ambient temperature.

   NOTE: Cooling required may be limited to that which will limit rate of chamber heating to 25°F. to 50°F. per hour and will prevent chamber temperature from exceeding the preselected sterilization temperature. As an operating plan this same limitation may be placed on step (6) of the ETO/Freon cycle when it is to be followed by dry heat.

3. Raise the chamber temperature, at a rate of 25°F. to 50°F.. per hour, to the preselected temperature in the range of 70°F. to 300°F. maintaining chamber pressure by bleed-off.

4. Maintain the selected chamber temperature for the specified period. Typical periods are 22 hours at 275°F. and 336 hours at 221°F., when temperature is measured at the coldest point on the equipment in the chamber. At temperatures of 200°F. to 300°F., the chamber relative humidity shall be less than 1%. The chamber pressure shall be maintained, at high temperature, by make-up with sterile nitrogen.

5. At the completion of the high temperature dwell, return chamber temperature to ambient at a rate of 25°F. to 50°F. per hour, maintaining chamber pressure by make-up with sterile nitrogen. When the chamber has been returned to room ambient, the relative humidity of the chamber atmosphere shall be 20% to 60%.

   NOTE: It shall be possible to maintain the chamber for an extended period in the state it is left in following step 5 by make-up with sterile nitrogen.

D. Shut Down

1. Discontinue laminar flow.

2. Bleed-off the chamber pressure to eliminate the pressure gradient across the door seals.

3. Disconnect the thermocouple from the chamber contents.

4. Shut off all main chamber equipment.

5. Open one end door and remove the contents of the chamber, then close the door.

III. AUXILIARY CHAMBER OPERATION

The operation of the auxiliary chamber is the same as the operation of the main chamber with the following exceptions:

1. The auxiliary chamber recirculating flow is not laminar.

2. In operation, the auxiliary chamber pressure will be 2" to 3" of water above ambient, (i.e., 1" to 2" of water below the main chamber).

3. Thermocouples can be removed from the contents only after the chamber door is opened.

4. To pass sterilized equipment into the main chamber, the auxiliary chamber pressure must be brought up to 4" of water above ambient and equalized with the main chamber pressure before opening the door into the main chamber.

IV. AUTOCLAVE OPERATIONS

There are two types of autoclave operating cycles; one for a dry load and one for a liquid load .

A. Set-Up

1. Place equipment to be sterilized in the autoclave in such a manner as to maximize contact of the autoclave atmosphere with the equipment. Connect thermocouples to the thermocouple junction panel and attach the sensing end to the equipment.

2. Close and seal the end doors of the autoclave (applies to outer door only if inner door is already closed).

B. Dry Load Cycle

1. Perform A(1) and (2) above.

2. Let in steam and bring autoclave up to the preselected temperature in the range of 216°F. to 270°F. While steam in being admitted, monitor for steam leaks around doors and seals.

3. Maintain the selected autoclave temperature for a period of 5 minutes to 3 hours nominal (5 minutes at 270°F; 3 hours at 216°F.)

4. Exhaust steam rapidly to ambient pressure (2 minutes nominal).

5. Fill the autoclave with sterile nitrogen; flush and refill with sterile nitrogen to 2" to 3" of water above ambient (nominally 20 gas changes).

6. Allow chamber to cool to ambient temperature maintaining chamber pressure by make-up with sterile nitrogen.

C. Wet Load Cycle

1. Perform A(1) and (2) above.

2. Purge the autoclave with steam and bring autoclave up to the preselected temperature in the range of 216°F. to 270°F. While steam is being admitted, monitor for steam leaks around doors and seals.

3. Maintain the selected autoclave temperature for a period of 5 minutes to 3 hours nominal (5 minutes at 270°F; 3 hours at 216°F.)

4. Exhaust steam slowly to 2" to 3" of water above ambient (exhaust in 8 minutes minimum, 20 minutes maximum).

5. Purge the autoclave with sterile nitrogen maintaining a pressure of 2" to 3" of water above ambient.

6. Allow chamber to cool to ambient temperature maintaining chamber pressure by make-up with sterile nitrogen.

D. Transfer to Main Chamber

1. Raise autoclave pressure with sterile nitrogen to 4" of water and equalize with main chamber pressure.

2. Open autoclave inner door and slide autoclave rack into main chamber.

3. Disconnect thermocouples from equipment, remove equipment from rack, and push rack and thermocouples back into autoclave.

4. Close and seal autoclave inner door.

5. Reduce autoclave pressure to ambient by bleed-off through the vacuum pump.

APPENDIX C. TEST SAMPLE TEST REPORT

LABAN NO. 170-145
DATE 9/25/65

PART - Triggered Multivibrator
PGM - A/S
MFG - Breadboard (Proto Type)
FR - Not Applicable
DES - Not Applicable
DWG - None

STATUS

On 9/20/65 the above prototype triggered multivibrator demonstration test circuit was delivered to the Parts Investigation Laboratory via J. Crawford of TR&A. Testing was initiated in order to demonstrate the capability of this unit to withstand a temperature soak at +135°C (275°F). The sample circuit was soaked at the prescribed temperature for 24 hours and subsequently subjected to a 20 hour operational life test.

INSTRUCTIONS

1. Operate and photograph input and output waveforms on dual trace scope.
2. Soak test circuit for 24 hours at +135°C (non-operating)
3. Repeat Instruction #1.
4. Operate test circuit for 20 hours (accumulated hours of operation) repeating Instruction #1 every two hours.

TEST AND MEASUREMENTS

The test instructions were carried out in their prescribed sequence.
The amplifier of the dual trace oscilloscope used to monitor the input and output waveforms was checked and calibrated with the internal calibration of two similar oscilloscopes.
Monitored oven temperature, during the temperature soak period of the test, ranged from 272 to 276°F.
Eight photographs were taken of the input and output waveforms as produced by the sample circuit at the following times and scope settings.

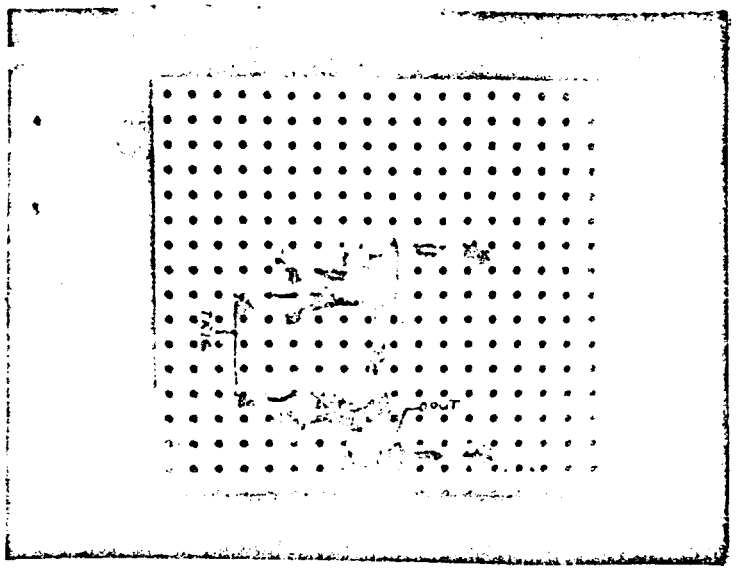
PHOTO #	TIME IN TEST	SCOPE SETTING *
1	Pre Temp. Soak	2V/cm, 0.1 sec/cm
2	Initial Post Temp. Soak (After 5 minutes operation)	2V/cm, 0.1 sec/cm
3	After 2 hours operation	2V/CM, 0.1 sec/cm
4	After 4 hours operation	2V/CM, 0.1 sec/cm
5	After 6 hours operation	2V/cm, 0.1 sec/cm
6	After 10 hours operation	2V/cm, 0.1 sec/cm
7	After 16 hours operation	2V/cm, 0.1 sec/cm
8	After 20 hours operation (End of Test)	2V/cm, 0.1 sec/cm

* Both Input (sawtooth in shape) and output (square in shape) signals were fed into a Tektronix plug-in amplifier Model CA operated in the chopped mode. The waveforms were superimposed upon each other for display on the oscilloscope screen.

RESULTS AND CONCLUSIONS

The sample prototype circuit remained operable throughout the testing effort. No significant or detectable changes were evidenced in either the pulse shapes, signal levels, or frequency rates of the test circuit waveforms as a result of being subjected to the specified test requirements.

D. M. Snyder



TEST CIRCUIT

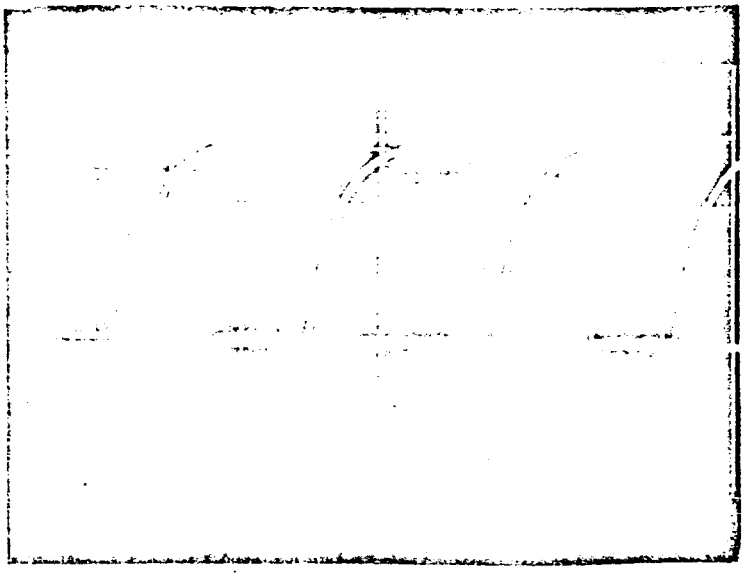


PHOTO #1 PRE TEMP SOAK

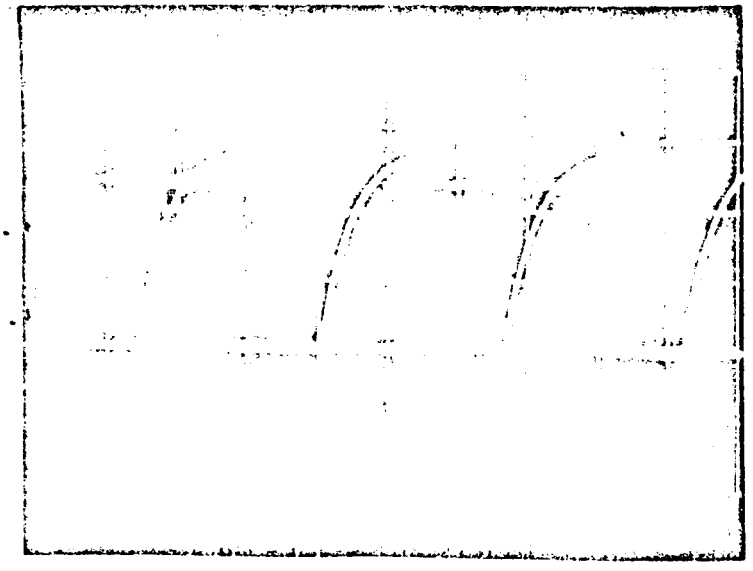


PHOTO #2 INITIAL POST TEMP. SOAK

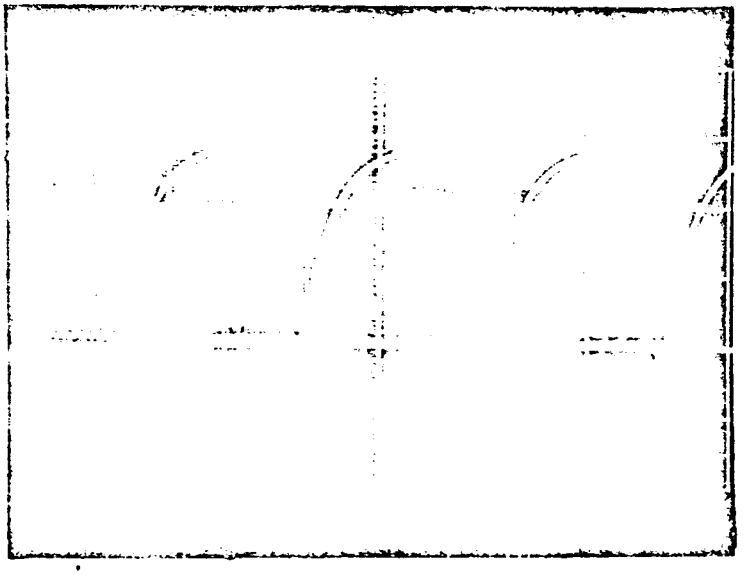


PHOTO #4 AFTER 4 HOURS OPERATION

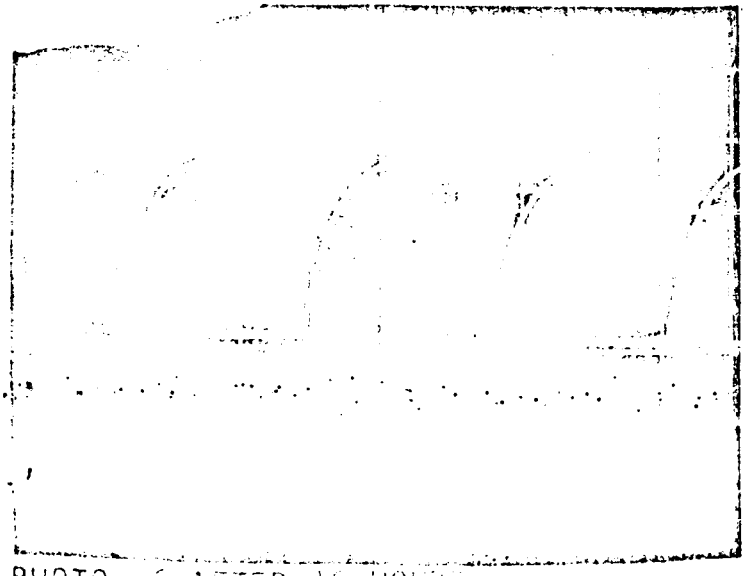


PHOTO #6 AFTER 10 HOURS OPERATION

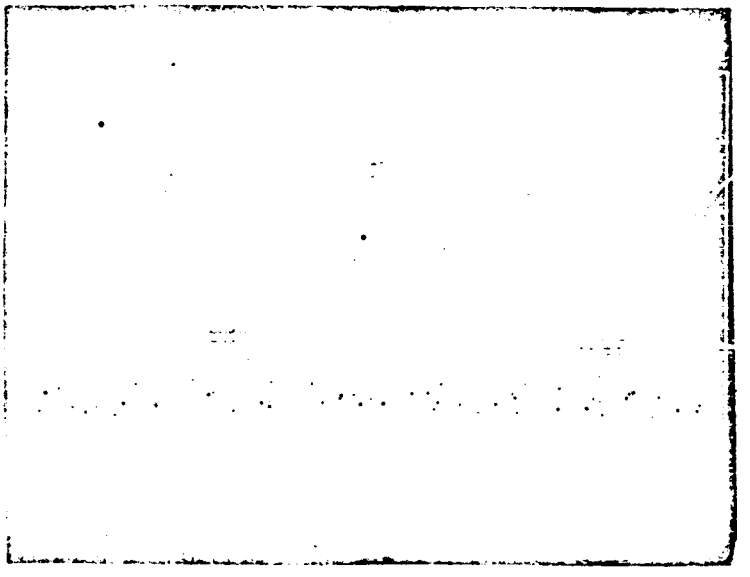


PHOTO #8 AFTER 20 HRS OPER. END OF TES